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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/826,290

Applicant(s)

DURHAM ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27, 33-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-50 are pending in the instant application.
2. Claims 28-32 are objected as being incomprehensible and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Accordingly, the claims 28-32 not been further treated on the merits.

Claims 1-27 and 33-50 are under examination in the instant office action.

3. Claims 1, 4, 11 are objected to as reciting an improper Markush Group. MPEP 803.02 states that

“Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.”

Applicant is advised that claims 1, 4, 11 are each improper Markush claims because the plurality of amino acid sequences recited in these claims lack a common utility which is based upon a shared structural feature lacking from the prior art.

Each of these proteins and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility

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which is lacking from those prior art proteins or nucleic acids. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

I to CXCI. Claims 1-3, in so far as they are drawn to a method for screening of Alzheimer's Disease by analyzing a test sample to generate a two-dimensional array of **any one** of the one hundred ninety one Alzheimer's Disease-Associated Features (AFs) recited therein, classified in class 530, subclass 412, for example. For example, Invention I consists of claims 1-3 only in so far as they encompass a method for screening of Alzheimer's Disease by analyzing a test sample to generate a two-dimensional array of AF-1. Invention CXCI consists of claims 1-3 only in so far as they encompass a method for screening of Alzheimer's Disease by analyzing a test sample to generate a two-dimensional array of AF-191.

CXCII to CDXXXIX. Claims 4-10, in so far as they are drawn to a method for screening of Alzheimer's Disease by detecting **any one** of two hundred forty eight Alzheimer's Disease-Associated Protein Isoforms (APIs) recited therein, classified in class 435, subclass 7.1, for example.

CDXL to DCLXXXVII. Claims 11-13, in so far as they are drawn to a preparation comprising **any one** of two hundred forty eight APIs recited therein, classified in class 530, subclass 300, for example.

DCLXXXVIII. Claims 14, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:467, classified in class 530, subclass 350, for example.

DCLXXXIX. Claims 15, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:479, classified in class 530, subclass 350, for example.

DCXC. Claims 16, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:470, classified in class 530, subclass 350, for example.

DCXCI. Claims 17, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:482, classified in class 530, subclass 350, for example.

DCXCII. Claims 18, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:473, classified in class 530, subclass 350, for example.

DCXCIII. Claims 19, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:485, classified in class 530, subclass 350, for example.

DCXCIV. Claims 20, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:476, classified in class 530, subclass 350, for example.

DCXCV. Claims 21, 22, 27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:488, classified in class 530, subclass 350, for example.

DCXCVI. Claims 14, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:467 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCXCVII. Claims 15, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:479 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCXCVIII. Claims 16, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:470 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCXCIX. Claims 17, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:482 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCC. Claims 18, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:473 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCCI. Claims 19, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:485 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCCII. Claims 20, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:476 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCCIII. Claims 21, 23-24, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:488 and SEQ ID NO:464, classified in class 530, subclass 350, for example.

DCCIV. Claims 25-27, drawn to a preparation comprising a protein having a partial sequence of SEQ ID NO:464, classified in class 530, subclass 350, for example.

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DCCV. Claims 33, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:469, classified in class 536, subclass 23.5, for example.

DCCVI. Claims 34, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:481, classified in class 536, subclass 23.5, for example.

DCCVII. Claims 35, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:472, classified in class 536, subclass 23.5, for example.

DCCVIII. Claims 36, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:484, classified in class 536, subclass 23.5, for example.

DCCIX. Claims 37, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:475, classified in class 536, subclass 23.5, for example.

DCCX. Claims 38, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:478, classified in class 536, subclass 23.5, for example.

DCCXI. Claims 39, 41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:487, classified in class 536, subclass 23.5, for example.

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DCCXII. Claims 40-41, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:489, classified in class 536, subclass 23.5, for example.

DCCXIII. Claims 43, 50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:469, classified in class 536, subclass 23.5, for example.

DCCXIV. Claims 44, 50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:481, classified in class 536, subclass 23.5, for example.

DCCXV. Claims 45, 50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:472, classified in class 536, subclass 23.5, for example.

DCCXVI. Claims 46, 50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:484, classified in class 536, subclass 23.5, for example.

DCCXVII. Claims 47, 50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:475, classified in class 536, subclass 23.5, for example.

DCCXVIII. Claims 48, 50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:478, classified in class 536, subclass 23.5, for example.



DCCXIX. Claims 49-50, drawn to an isolated nucleic acid molecule that hybridizes to nucleic acid of SEQ ID NO:487, classified in class 536, subclass 23.5, for example.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I to CDXXXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

5. The preparations comprising proteins that are inventions CDXL to DCCIV, the preparations comprising nucleic acids that are inventions DCCV to DCCXIX are four hundred ninety two different chemical compositions each of which can be made and used without each other. Lack of unity is shown by the fact that these four hundred ninety two different compositions lack a common utility based upon a shared structural feature lacking from the prior art.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original

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signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
June 24, 2002

OC

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800